



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

~~DOCUMENT CONTAINS CONFIDENTIAL BUSINESS INFORMATION~~

DP BARCODE No.: D445396; FILE SYMBOL No.: 71368-113; PRODUCT NAME: Panther SC – AG
Herbicide; DECISION No.: 537232; PC Code(s): 129034; ACTION CODE: R340; FOOD Use: Yes;
COMPANY: NuFarm Incorporation

DATE OUT: March 12, 2018

SUBJECT: End Use Product Chemistry Review
Product Name: Panther SC- AG herbicide

FROM: Shyam Mathur, Ph. D
Team Leader
Chemistry, Inerts & Toxicology Assessment Branch (CITAB) /RD (7505P)

TO: Nathan Mellor / Shaja Joyner, RM 20; Fungicide-Herbicide Branch / RD (7505P)

INTRODUCTION:

The registrant has submitted an application to amend the registration of the end use product Panther SC-AG Herbicide. The amendment involved:

- Change the label claim from 44.0% to 41.4%
- Change the NC of the AI to 41.4% in basic & alternate CSF's
- Submission of revised group A product chemistry data to support the revised CSF's

The registrant has submitted a CSF for basic formulation and alternate formulation CSF#1 (both dated December 7, 2017) and the supporting revised group A product chemistry data with MRID No(s). 50456001 and the group B data with MRID No. 49456102. CITAB has been asked to determine the acceptability of the proposed basic CSF and the alternate CSF #1 and the supporting product chemistry.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient(s): Flumioxazin (41.4%)
2. Has the registrant claimed substantial similarity to a registered product?
☐ Yes; ☒ No; ☐ NA; if yes give the registration number of the cited product.

EPA Reg. No:

3. All of the source materials of the active ingredient are derived from registered sources- ☒ Yes ☐ No
4. All inert ingredients have been screened by CITAB (Inert group) and found to be approved for the proposed labeled uses.

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5. Confidential Statement of Formula(s):

☒ Basic - Dated: 12-07-2017; Re-submitted - Dated:

☒ Alternate CSF #1 – Dated: 12-07-2017; Re-submitted alt CSF – Dated:

Alternate CSF(s) complies with 40CFR§152.43: ☒ Yes; ☐ No; ☐ NA

6. Product label

- a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concurs with product label (PR Notice 91-2).

☒ Yes; ☐ No; if not, explain below:

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredients)

☒ Yes; ☐ No; if not, explain below:

Metallic equivalent:	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> NA
Soluble arsenic:	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> NA
Isomeric ratios:	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> NA
Acid Equivalent:	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> NA
acid equivalent =		

- b. Health related sub statements: Product contains?

Petroleum distillate at > 10%:	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> NA
Methanol at > 4%:	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> NA
Sodium nitrate/Sodium nitrite	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> NA

- c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?

☒ Yes; ☐ No

Note: Incompatible with oxidizing agents

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?

☐ Yes; ☐ No; ☒ NA; if not, explain below

- d. Label requires an additional Storage and Disposal statement:

☐ Yes; ☒ No; if yes explain below:

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7. Group **A**: Product Chemistry Data submitted

CITAB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		CITAB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		X		A	50456001
830.1600	Description of materials used to produce the product		X		A	50456001
830.1650	Description of formulation process		X		A	50456001
830.1670	Discussion on the formation of impurities		X		A	50456001
830.1700	Preliminary analysis				NA	
830.1750	Certified limits (158.350)	Standard certified limits	X		A	Basic CSF dated 12-07-2017
		Proposed Limits				
		Justification for wider limits				
830.1800	Enforcement analytical method		X		A	50456001 HPLC-UV (288 nm) with external standard calibration.

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress, NA = Not Applicable; U = Upgradeable.

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8. Group B: Product chemistry data submitted

Guideline No.	Study Title	Value or Qualitative Description	CITAB's Assessment of Data	MRID Nos.
830.6303	Physical State	Liquid at 25.2°C	A	49456102
830.6315	Flammability	None of the components in the TS are not flammable	NA	Data matrix dated 12-07-2017
830.6316	Explodability	Neither technical or the inert ingredients are considered as potentially explosive	NA	Data Matrix Dated 12-07-2017
830.7000	pH	6.38 at 25°C (1% dispersion)	A	49456102
830.7300	Density (units)	1.157 g/cc (9.66 lbs/gal)@ 24°C	A	49456102
830.7100	Viscosity	322.0 cPs /100 speed/ 24°C 266.8 cPs / 100 speed /42°C	A	49456102
830.6317	Storage stability	Study in progress	I	Data Matrix Dated 12-07-2017
830.6320	Corrosion characteristics	Study in progress	I	Data Matrix Dated 12-07-2017
830.6314	Oxidation/Reduction	TS was found to be compatible with water, 5% ammonium phosphate, Fe powder, and Aromatic 200 Fluid. TS is Incompatible with 5 % KMnO ₄	A	49456102

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request, NA = Not applicable, I = In progress; U = Upgradeable; I = In progress

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COMPANY: NuFarm Incorporation

CONCLUSIONS:

CITAB has reviewed the product chemistry data submitted for the end-use product and has concluded that:

A. Substantial similarity to the cited product (Reg. No.) from Product chemistry view point

- ☐ Similar
- ☐ Not similar
- ☒ Not Applicable

B. Confidential Statement of formula

- 1. Basic CSF (dated: 12-07-2017)
 - ☒ Acceptable
 - ☐ Not Acceptable:
 - ☐ Not Applicable
- 2. Alternate CSF #1 (dated: 12-07-2017)
 - ☒ Acceptable
 - ☐ Not Acceptable:
 - ☐ Not Applicable

C. Group A Product Chemistry Data

- ☒ Acceptable
- ☐ Acceptable with the exception of the guideline:
- ☐ Not acceptable
- ☐ Not required
- ☐ Data cited

D. Group B Product chemistry data

- ☐ Acceptable
- ☐ Not acceptable
- ☒ Acceptable with the exception of the guidelines 830.6317 & 830.6320
- ☐ Not required
- ☐ Data cited for the guidelines
- ☐ Waiver requests: Acceptable ☐; Not Acceptable ☐; Not Applicable ☒

E. Product Label/Draft Label: Recommendations – ☒ Yes; No ☐

Note to PM: Since the product was found to be incompatible with oxidizing agents, the registrant is recommended to add the following statement under Physical-Chemical Hazards on the product label:

“Do not mix or allow coming in contact with oxidizing agent. Hazardous Chemical reaction may occur”



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DP BARCODE No.: D445396; **FILE SYMBOL No.:** 71368-113 (screen); **PRODUCT NAME:** Panther SC-AG Herbicide; **DECISION No.:** 537232; **PC Code(s):** 129034; **ACTION CODE:** R340; **FOOD Use:** Yes

DATE OUT: February 8, 2018

SUBJECT: 45/90-day screen for end use product "Panther SC-AG Herbicide"

FROM: Shyam Mathur, Product Chemistry Team Leader, CITAB / RD (7505P)

SRM

TO: Nathan Mellor / Shaja Joyner, RM 20; Fungicide-Herbicide Branch / RD (7505P)

Company Name: NuFarm Incorporation
Active Ingredient(s): Flumioxazin (41.4%)
MRID No(s): 50456001 & 49456102

CONCLUSION:

Deficiencies: No

(if there are deficiencies they are indicated below each heading as Note 1, Note 2 Etc)

Group A: All required data submitted

Group B: All required data submitted.

CSF: Revised Basic CSF & Alt CSF#1 (both dated 12-07-2017) submitted

DRAFT PRODUCT LABEL: Submitted

Note to PM: Since the product was found to be incompatible with oxidizing agents, the registrant is recommended to add the following statement under Physical-Chemical Hazards on the product label:

"Do not mix or allow coming in contact with oxidizing agent. Hazardous Chemical reaction may occur"

Note to PM: If the deficiencies are found in the screen results, please inform the registrant and bring back to the author of this report the corrected deficiencies in response to 10 day letter. The corrected deficiencies will be attached to the original bean, if the data package is still in CITAB. New Bean is required in case the bean has been closed by CITAB. Thank you.